

#12



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

SETTE *et al.*

Appl. No. 09/412,863

Filed: October 5, 1999

For: **Inducing Cellular Immune  
Responses To Human  
Immunodeficiency Virus-1 Using  
Peptide And Nucleic Acid  
Compositions**

Confirmation No.

Art Unit: 1644

Examiner: Schwadron, R.

Atty. Docket: 2060.0040005/EKS/HCC

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TECH CENTER 1600/2900

### Provisional Election Of Species

Commissioner for Patents  
Washington, D.C. 20231

Sir:

The Examiner has required an election of species. To be fully responsive, Applicants hereby provisionally elect (a) the peptide VLAEAMSQV (SEQ ID NO:14422), and (b) the composition containing a T helper epitope. In view of this provisional election, new claims 71-107, 129-134, 165-170, 203-208, 235-240, and 260-265, added in the accompanying Third Preliminary Amendment, read on the provisionally elected species. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

Applicants assert the right to claim additional species in the event that generic claims thereto are found to be allowable in accordance with 37 C.F.R. § 1.141(a). This election is made without traverse. Consideration and allowance of all pending claims are respectfully requested.

#### *Interview*

Applicants thank Examiners Schwadron and DiBrino for the courteous and helpful interview extended to Bob Chesnut, Alex Alessandro, and Grace Doh, all of Epimmune, and Applicants' representatives Eric Steffe and Helene Carlson on January 10, 2002.

As discussed during the interview, Applicants have organized the independent claims to include peptides having the same priority dates, to aid in examination. Thus, although the Amendment submitted herewith contains several independent claims, Applicants respectfully request examination of a reasonable number of peptides, notwithstanding the fact that they are recited in several independent claims.

Applicants also provide herewith information obtained from searches performed for the claimed peptides, for the convenience of the Examiner. Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this

information may not be enabling for the teachings purportedly offered. This information should not be construed as a representation that information more material to the examination of the present patent application does not exist, and Applicants request that the Examiner perform an independent search of the claimed subject matter.

It is believed that extensions of time are not required, beyond those that may otherwise be provided for in accompanying documents. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor are hereby authorized to be charged to our Deposit Account No. 19-0036. A duplicate copy is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Helene C. Carlson  
Agent for Applicants  
Registration No. 47,473

Date: February 14, 2002  
1100 New York Avenue, N.W.  
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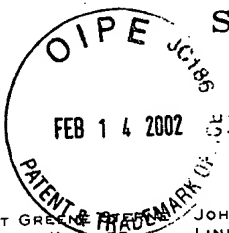
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**Table 1 – Support for claims**

<b><u>Support</u></b>	<b><u>Appl. No. 09/412,863</u></b>	<b><u>Appl. No. 08/103,396</u></b>
T helper peptide	Page 51, lines 12-14	Page 22, lines 18-21, 34-36
Spacer	Page 51, line 17	Page 22, line 21
Carrier	Page 43, line 30	Page 29, line 27
Lipid	Page 52, line 25	Page 23, line 3
Fusion protein	Page 38, line 31 Page 39, line 7 Page 43, lines 21-33 Page 53, lines 11-16 Page 54, lines 26-27	Page 24, line 25 Page 23, lines 31-38 Page 29, lines 27-38
Homopolymer	Page 43, line 22	Page 29, line 27
Heteropolymer	Page 43, line 22	Page 29, line 27
Composition	Page 6, line 13 Page 9, line 7	Page 23, line 1 Page 25, line 13
Pharmaceutical composition	Page 12, line 21	Page 29, line 2
Liposome	Page 43, line 12	Page 28, line 1
Vaccine	Page 42, line 27	Page 29, line 24
Physiologically acceptable diluent	Page 43, line 34	Page 29, line 38
One or more second peptides	Page 38, line 24 Page 38, line 31 Page 43, line 21	Page 24, line 25
15, 11, 10, 9 amino acids in length	Page 12, lines 13-18	Page 4, lines 10-17
Linker	Page 53, lines 11-16	Page 23, lines 31-38

**Table 2 - Peptides**

<b><u>SEQ ID NO.</u></b>	<b><u>Antigen</u></b>	<b><u>Priority Date</u></b>	<b><u>Priority Appl. No.</u></b>
14422	HIV gag 386	3/5/93	08/027,146
14457	HIV pol 684	8/6/93	08/103,396
14458	HIV gag 317	8/6/93	08/103,396
14459	HIV pol 368	8/6/93	08/103,396
14460	HIV pol 295	8/6/93	08/103,396
14461	HIV pol 533	8/6/93	08/103,396
14463	HIV pol 530	8/6/93	08/103,396
14466	HIV env 671	8/6/93	08/103,396
14439	HIV pol 722	8/6/93	08/103,396
14440	HIV pol 971	8/6/93	08/103,396
14441	HIV pol 353	8/6/93	08/103,396
14442	HIV pol 347	8/6/93	08/103,396
14445	HIV env 47	8/6/93	08/103,396
14438	HIV pol 929	8/9/93	08/103,396
14446	HIV nef 100	11/29/93	08/159,339
14432	HIV env 134	3/4/94	08/205,713
14293	HIV env 814	3/4/94	08/205,713



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\*LIMITED TO MATTERS  
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FEDERAL COURTS & AGENCIES  
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February 14, 2002

WRITER'S DIRECT NUMBER:  
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INTERNET ADDRESS:  
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Commissioner for Patents  
Washington, D.C. 20231

Re: U.S. Utility Patent Application  
Appl. No. 09/412,863; Filed: October 5, 1999  
For: **Inducing Cellular Immune Responses To Human Immunodeficiency  
Virus-1 Using Peptide And Nucleic Acid Compositions**  
Inventors: SETTE *et al.*  
Our Ref: 2060.0040005/EKS/HCC  
Art Unit: 1644

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Fee Transmittal Form (PTO/SB17);
2. Petition For Extension of Time Under 37 C.F.R. § 1.136(a)(1);
3. Provisional Election of Species;
4. Third Preliminary Amendment with three (3) attachments;
5. A copy of an executed Revocation of Prior Power of Attorney and Appointment of New Attorneys of Record;
6. A copy of an executed Certificate Under 37 C.F.R. § 3.73(b); and

Commissioner for Patents  
February 14, 2002  
Page 2

7. One return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Helene C. Carlson  
Agent for Applicants  
Registration No. 47,473

EKS/HCC/eak  
Enclosures

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<div style="display: flex; align-items: center; justify-content: center;"> <div style="border: 2px solid black; border-radius: 50%; padding: 10px; margin-right: 10px; text-align: center;"> <b>PTO</b> FEB 14 2002 <b>PATENT &amp; TRADEMARK OFFICE</b> </div> <div> <h2 style="margin: 0;">FEE TRANSMITTAL</h2> <h3 style="margin: 0;">for FY 2002</h3> <p style="font-size: small; margin: 5px 0;">Patent fees are subject to annual revision.</p> </div> </div>		Complete if Known	
		Application Number	09/412,863
		Filing Date	October 5, 1999
		First Named Inventor	SETTE
		Examiner Name	Schwadron, R.
		Group Art Unit	1644
		Attorney Docket No.	2060.0040005/EKS/HCC
TOTAL AMOUNT OF PAYMENT		(\$) 2,384.00	

METHOD OF PAYMENT (check one)	FEE CALCULATION (continued)																																																																																																																																																																																				
<p>1. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge indicated fees and credit any overpayment to:</p> <div style="border: 1px solid black; padding: 5px; margin-top: 5px;">             Deposit Account Number: 19-0036              Deposit Account Name: Sterne, Kessler, Goldstein &amp; Fox P.L.L.C.           </div> <p><input type="checkbox"/> Charge Any Additional Fee Required Under 37 CFR §§ 1.16 and 1.17</p> <p><input checked="" type="checkbox"/> Applicant claims small entity status See 37 CFR 1.27</p> <p>2. <input type="checkbox"/> Payment Enclosed:</p> <p><input type="checkbox"/> Check   <input type="checkbox"/> Credit card   <input type="checkbox"/> Money Order   <input checked="" type="checkbox"/> Other*</p> <p style="font-size: x-small;">*Charge any deficiencies or credit any overpayments in the fees or fee calculations of Parts 1, 2 and 3 below to Deposit Account No. 19-0036.</p>	<p>3. ADDITIONAL FEES</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;">Large</th> <th style="width: 10%;">Entity</th> <th style="width: 10%;">Small</th> <th style="width: 10%;">Entity</th> <th style="width: 50%;">Fee Description</th> <th style="width: 10%;">Fee paid</th> </tr> <tr> <th>Fee Code</th> <th>Fee (\$)</th> <th>Fee Code</th> <th>Fee (\$)</th> <th></th> <th></th> </tr> </thead> <tbody> <tr><td>105</td><td>130</td><td>205</td><td>65</td><td>Surcharge - late filing fee or oath</td><td></td></tr> <tr><td>127</td><td>50</td><td>227</td><td>25</td><td>Surcharge - late provisional filing fee or cover sheet</td><td></td></tr> <tr><td>139</td><td>130</td><td>139</td><td>130</td><td>Non-English specification</td><td></td></tr> <tr><td>147</td><td>2,520</td><td>147</td><td>2,520</td><td>For filing a request for <i>ex parte</i> reexamination</td><td></td></tr> <tr><td>112</td><td>920*</td><td>112</td><td>920*</td><td>Requesting publication of SIR prior to Examiner action</td><td></td></tr> <tr><td>113</td><td>1,840*</td><td>113</td><td>1,840*</td><td>Requesting publication of SIR after Examiner action</td><td></td></tr> <tr><td>115</td><td>110</td><td>215</td><td>55</td><td>Extension for reply within first month</td><td></td></tr> <tr><td>116</td><td>400</td><td>216</td><td>200</td><td>Extension for reply within second month</td><td></td></tr> <tr><td>117</td><td>920</td><td>217</td><td>460</td><td>Extension for reply within third month</td><td></td></tr> <tr><td>118</td><td>1,440</td><td>218</td><td>720</td><td>Extension for reply within fourth month</td><td></td></tr> <tr><td>128</td><td>1,960</td><td>228</td><td>980</td><td>Extension for reply within fifth month</td><td>980.00</td></tr> <tr><td>119</td><td>320</td><td>219</td><td>160</td><td>Notice of Appeal</td><td></td></tr> <tr><td>120</td><td>320</td><td>220</td><td>160</td><td>Filing a brief in support of an appeal</td><td></td></tr> <tr><td>121</td><td>280</td><td>221</td><td>140</td><td>Request for oral hearing</td><td></td></tr> <tr><td>138</td><td>1,510</td><td>138</td><td>1,510</td><td>Petition to institute a public use proceeding</td><td></td></tr> <tr><td>140</td><td>110</td><td>240</td><td>55</td><td>Petition to revive - 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late filing fee or oath		127	50	227	25	Surcharge - late provisional filing fee or cover sheet		139	130	139	130	Non-English specification		147	2,520	147	2,520	For filing a request for <i>ex parte</i> reexamination		112	920*	112	920*	Requesting publication of SIR prior to Examiner action		113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action		115	110	215	55	Extension for reply within first month		116	400	216	200	Extension for reply within second month		117	920	217	460	Extension for reply within third month		118	1,440	218	720	Extension for reply within fourth month		128	1,960	228	980	Extension for reply within fifth month	980.00	119	320	219	160	Notice of Appeal		120	320	220	160	Filing a brief in support of an appeal		121	280	221	140	Request for oral hearing		138	1,510	138	1,510	Petition to institute a public use proceeding		140	110	240	55	Petition to revive - unavoidable		141	1,280	241	640	Petition to revive - unintentional		142	1,280	242	640	Utility issue fee (or reissue)		143	460	243	230	Design issue fee		144	620	244	310	Plant issue fee		122	130	122	130	Petitions to the Commissioner		123	130	123	130	Petitions related to provisional applications		126	180	126	180	Submission of Information Disclosure Stmt		581	40	481	40	Recording each patent assignment per property (times number of properties)		146	740	246	370	Filing a submission after final rejection (37 CFR 1.129(a))		149	740	249	370	For each additional invention to be examined (37 CFR 1.129(b))		179	740	279	370	Request for Continued Examination (RCE)		169	900	169	900	Request for expedited examination of a design application	
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<p><b>FEE CALCULATION</b></p> <p><b>I. BASIC FILING FEE</b></p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Large Fee Code</th> <th>Entity Fee (\$)</th> <th>Small Fee Code</th> <th>Entity Fee (\$)</th> <th>Fee Description</th> <th>Fee Paid</th> </tr> </thead> <tbody> <tr><td>101</td><td>740</td><td>201</td><td>370</td><td>Utility filing fee</td><td></td></tr> <tr><td>106</td><td>330</td><td>206</td><td>165</td><td>Design filing fee</td><td></td></tr> <tr><td>107</td><td>510</td><td>207</td><td>255</td><td>Plant filing fee</td><td></td></tr> <tr><td>108</td><td>740</td><td>208</td><td>370</td><td>Reissue filing fee</td><td></td></tr> <tr><td>114</td><td>160</td><td>214</td><td>80</td><td>Provisional filing fee</td><td></td></tr> </tbody> </table> <p style="text-align: right;">SUBTOTAL (1) (\$) 0</p> <p><b>2. EXTRA CLAIM FEES</b></p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th>Extra</th> <th>Fee from below</th> <th>Fee Paid</th> </tr> </thead> <tbody> <tr> <td>Total Claims 195</td> <td>-39** = 156</td> <td>X 9 =</td> <td>1,404.00</td> </tr> <tr> <td>Indep. Claims 6</td> <td>-11** = 0</td> <td>X 42 =</td> <td>-0-</td> </tr> <tr> <td>Multiple Dependent</td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Large Fee Code</th> <th>Entity Fee (\$)</th> <th>Small Fee Code</th> <th>Entity Fee (\$)</th> <th>Fee Description</th> </tr> </thead> <tbody> <tr><td>103</td><td>18</td><td>203</td><td>9</td><td>Claims in excess of 20</td></tr> <tr><td>102</td><td>84</td><td>202</td><td>42</td><td>Independent claims in excess of 3</td></tr> <tr><td>104</td><td>280</td><td>204</td><td>140</td><td>Multiple dependent claim</td></tr> <tr><td>108</td><td>84</td><td>209</td><td>42</td><td>**Reissue independent claims over original patent</td></tr> <tr><td>110</td><td>18</td><td>210</td><td>9</td><td>**Reissue claims in excess of 20 and over original patent</td></tr> </tbody> </table> <p style="text-align: right;">SUBTOTAL (2) (\$) 1,404.00</p> <p style="font-size: x-small;">** or number previously paid, if greater; For Reissues, see above</p>	Large Fee Code	Entity Fee (\$)	Small Fee Code	Entity Fee (\$)	Fee Description	Fee Paid	101	740	201	370	Utility filing fee		106	330	206	165	Design filing fee		107	510	207	255	Plant filing fee		108	740	208	370	Reissue filing fee		114	160	214	80	Provisional filing fee			Extra	Fee from below	Fee Paid	Total Claims 195	-39** = 156	X 9 =	1,404.00	Indep. Claims 6	-11** = 0	X 42 =	-0-	Multiple Dependent				Large Fee Code	Entity Fee (\$)	Small Fee Code	Entity Fee (\$)	Fee Description	103	18	203	9	Claims in excess of 20	102	84	202	42	Independent claims in excess of 3	104	280	204	140	Multiple dependent claim	108	84	209	42	**Reissue independent claims over original patent	110	18	210	9	**Reissue claims in excess of 20 and over original patent	<p style="text-align: right;">SUBTOTAL (3) (\$) 980.00</p>																																																																																																		
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SUBMITTED BY		Complete (if applicable)	
Name (Print/Type)	Helene C. Carlson	Registration No. (Attorney/Agent)	47,473
Signature		Telephone	202-371-2600
		Date	February 14, 2002